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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,817	02/26/2002	George F. Schreiner	SCIOS.002C1	8504

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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/083,817	SCHREINER ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 1 has been amended in the response of 28 February 2007. Claims 1-10 are currently pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 28 February 2007 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Guyton (Textbook of Medical Physiology, 8th edition, W.B. Saunders Company, pages 209-218, 1991) in view of Roberts et al. (J. Cell Sci. 108: 2369-2379, 1995) for the reasons of record in the previous Office action.

Applicant argues that there is no motivation to combine the two references. Applicant asserts that there is nothing in Roberts that teaches or suggests that VEGF is capable of increasing the renal blood flow. However, Roberts was cited as teaching that VEGF induces endothelial fenestrae and increases vascular permeability to solutes. Because Guyton teaches that individuals with essential hypertension have an impaired ability to excrete salt and water, one would be motivated to administer VEGF because Roberts teaches that VEGF stimulates fenestration of the endothelium in the kidney glomeruli, which would increase the permeability of the endothelium and facilitate excretion of salt and water. Applicant's insistence that VEGF increase renal blood flow is misplaced because Guyton teaches that essential hypertension is generally treated by giving drugs that (1) increase renal blood flow and/or (2) decrease tubular reabsorption of salt and water (see page 218, column 1, paragraph 2). Because the administration of VEGF, as taught by Roberts et al., would promote excretion of salt and water from the tubules, this would be considered a treatment for hypertension.

Claims 1 and 5-9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Guyton (Textbook of Medical Physiology, 8th edition, W.B. Saunders Company, pages 209-218, 1991) in view of Hariawala et al. (J. Surg. Research 63: 77-82, 1996) further in view of Zioncheck et al. (U.S. Pat. No. 6,485,942) for the reasons of record in the previous Office action.

Applicant argues that Hariawala et al. does not teach administration of VEGF to patients with high blood pressure. Applicant is correct, otherwise the rejection would be

one of anticipation. Hariawala et al. was cited for the teaching that administration of VEGF reduces mean arterial blood pressure and causes significant vasodilation and hypotension.

Applicant argues that Hariawala et al. teaches away from the invention because the observed vasodilation was rapid and severe and because Hariawala et al. suggest that this would be a clinical problem. Applicant's argument has been fully considered, but is not persuasive. The skill in the art at the time of the instant invention is high. Hariawala et al. have identified a potential problem, but also offer the solution in the reference, which is to administer the VEGF at a lower dose and to avoid the effects of a bolus injection. The experimentation required to obtain a desired effect without severe hypotension would be routine in the art at the time the invention was made, absent evidence to the contrary.

Applicant argues that Zioncheck et al. does not cure the deficiencies of Hariawala et al. However, Zioncheck et al. was cited to teach various forms of VEGF were known and available, as well as the advantages of using VEGF121.

Claims 1 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Guyton (Textbook of Medical Physiology, 8th edition, W.B. Saunders Company, pages 209-218, 1991) in view of Hariawala et al. (J. Surg. Research 63: 77-82, 1996) further in view of Cid et al. (U.S. Pat. No. 5,318,957) for the reasons of record.

Applicant argues at page 6 that Hariawala et al. teach away from the claimed invention. These arguments are not persuasive for the reasons provided above.

Applicant argues that Cid et al. does not correct the deficiencies in Hariawala et al. However, Cid et al. was cited as teaching that angiogenic factors stimulate the formation new blood vessels and that these factors are useful for treatment of conditions involving angiogenesis, such as myocardial and cerebral infarctions, limb ischemia, wounds and vascular occlusion or stenosis. It also would have been *prima facie* obvious at the time of the instant invention to additionally administer an angiogenic factor in combination with VEGF because Cid et al. teach that angiogenic factors are useful for treatment of conditions which involve angiogenesis, and Guyton teach that hypertension can cause a number of conditions which involved angiogenesis. One would have been motivated to administer an angiogenic factor in combination with VEGF because Guyton teaches that secondary diseases/disorders can be caused by hypertension and because Cid et al. teach that administration of angiogenic factors would be beneficial for treatment of these conditions.

Applicant argues that there is no reason to combine an angiogenic factor with VEGF "just because hypertension sometimes leads to heart failure, stroke, or kidney failure". Applicant's argument has been fully considered, but is not persuasive. Guyton teaches that there are secondary diseases/ disorder which can be caused by hypertension. It is common in the art to not only treat the primary disease/disorder, but also the secondary conditions/symptoms as well. Because hypertension can also be associated with a number of conditions involving angiogenesis, it would have been prima facie obvious and one would have been motivated to administer an angiogenic factor in combination with VEGF because Guyton teaches that secondary

diseases/disorders can be caused by hypertension and because Cid et al. teach that administration of angiogenic factors would be beneficial for treatment of these conditions. Therefore, the invention as a whole would have been *prima facie* obvious at the time the invention was made, absent evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/749,706. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to treatment of hypertension by the administration of VEGF. The base claims differ in

wording, but the patient population which is being treated is the same and the same protein is being administered, therefore, the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud